

# **EXHIBIT 4**

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

- - -

3   IN RE:    ETHICON, INC.                   :   MDL NO. 2327  
4            PELVIC REPAIR SYSTEM               :  
5            PRODUCTS LIABILITY                 :  
6            LITIGATION                         :

- - -

7                   THIS DOCUMENT RELATES TO ALL CASES  
8                   AND VARIOUS OTHER CROSS-NOTICED ACTIONS

- - -

                  Wednesday, August 15, 2013

9                   VOLUME II

- - -

11                   CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

12  
13                   Videotaped Deposition of THOMAS A.  
14   BARBOLT, Ph.D., held at Riker Danzig Scherer Hyland  
15   Perretti LLP, Headquarters Plaza, One Speedwell Avenue,  
16   Morristown, New Jersey, on the above date, beginning at  
17   9:03 a.m., before Margaret M. Reihl, a Certified  
18   Realtime Reporter, Certified Court Reporter, and Notary  
19   Public.

- - -

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1                   Deposition Exhibit No. T-2115.)

2                   MR. THOMAS: Just for the record, you've  
3   marked this as 2115?

4   BY MR. THORNBURGH:

5   Q.       Yeah, I'm sorry. It's been marked -- the  
6   exhibit has been marked 2115 ETH.MESH.00863391.

7               And you see this is an e-mail from Dan Smith on  
8   February 27th, 2004, right?

9   A.       Yes.

10   Q.       And the subject line is "2 TVT complaints  
11   concerning allegedly brittle mesh."

12              You see that?

13   A.       Yes.

14   Q.       And as we did yesterday, I'd would like to turn  
15   to -- turn to the second page and we'll work backwards.

16              And the original e-mail is from Bernhard  
17   Fischer to Janice Burns with that same subject line,  
18   the importance is high, and Bernhard says or  
19   Mr. Fischer says to Janice Burns or discusses with  
20   Janice Burns two TVT complaints regarding mesh TVT Blue  
21   and the TVT obturator system.

22              And if you look down at the paragraph after  
23   that it says, "Dr. Mirna noticed that small blue  
24   particles kept falling off the mesh, as if the mesh was  
25   as he put it 'brittle'."

1 European countries?

2 A. I don't think I -- I don't recall that.

3 Q. Well, let's look at this, so you get some  
4 background, okay. So, again, I'm going to have you  
5 turn -- the Bates number is 03358217, and the subject  
6 is, as you can see on Page 1 on this May 1st, 2006  
7 e-mail, French standard on TVT and meshes.

8 And so if you turn with me to  
9 ETH.MESH.003358222, it's an e-mail from Scott Ciarrocca  
10 to a number of individuals directed to Xavier and  
11 Pascale. It says, looking into finding a way to give  
12 you specifics. It is unfortunately not straightforward  
13 to obtain all this. To be clear, we're talking about  
14 Prolene Gynemesh® Soft, the implantable materials, not  
15 the TVT or Prolift® devices.

16 Actually, let me -- if you go ahead to the very  
17 last page, sorry about that, 8224, the subject is AFNOR  
18 (ISO) Organization - Request.

19 You see that?

20 A. Yes.

21 Q. And it says -- it's an e-mail from Xavier at  
22 Gynecare France saying, over the last few months in our  
23 country we are -- we can observe a clear awareness from  
24 the KOLs and other surgeons in regard to what is or not  
25 a good prosthesis, both for SUI slings and prolapse

1 Q. There's going to be an inflammatory response to  
2 the particles that are loose with inside the woman's  
3 pelvis, right?

4 MR. THOMAS: Object to the form of the  
5 question.

6 THE WITNESS: Yes.

7 BY MR. THORNBURGH:

8 Q. And that inflammatory response can result in  
9 granuloma formation around each one of these particles  
10 contained within the woman's pelvis, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: Yes.

14 BY MR. THORNBURGH:

15 Q. So you're going to have -- essentially, you're  
16 going to end up having little granuloma covered  
17 particles, kind of like little BBs inside the pelvis of  
18 a woman's vagina?

19 MR. THOMAS: Object to form of the  
20 question.

21 THE WITNESS: No, not quite.

22 BY MR. THORNBURGH:

23 Q. Well, they're certainly going to form  
24 granulomas around each one of those particles?

25 MR. THOMAS: Object to form of the

1 question.

2 THE WITNESS: They will form the same  
3 kinds of granuloma around the particles as they do  
4 around each individual filament of the mesh.

5 BY MR. THORNBURGH:

6 Q. Right. So you're going to have additional  
7 granuloma formation around those particles?

8 A. Yes.

9 Q. And the body is going to react or is reacting  
10 to each one of those particles within the woman's  
11 vagina?

12 MR. THOMAS: Object to the form of the  
13 question.

14 THE WITNESS: They will be the particles  
15 within the tissues around the mesh.

16 BY MR. THORNBURGH:

17 Q. And, again, you were not asked to conduct a  
18 study looking specifically at the inflammatory response  
19 associated with those particles, correct?

20 A. That's correct.

21 Q. Handing you what's been premarked as Exhibit  
22 2119 a series of e-mails regarding this particle loss  
23 issue.

24 (Document marked for identification as  
25 Deposition Exhibit No. T-2119.)

1 Q. Preclinically in animals, you can -- I  
2 understand you've said it before, I'm asking you to say  
3 it again, in animals when you have this foreign body  
4 and you have additional foreign bodies from the  
5 particles that are lost during implantation of the  
6 device, each one of those particles as well as the  
7 actual full product mesh inserted in the patient or in  
8 an animal is going to trigger a foreign body response,  
9 right?

10 MR. THOMAS: Object to the form of the  
11 question.

12 THE WITNESS: Yes.

13 BY MR. THORNBURGH:

14 Q. An inflammatory response, correct?

15 A. Yes.

16 Q. Which will result in granuloma formation over  
17 each one of those particles and over the mesh?

18 MR. THOMAS: Object to the form of the  
19 question.

20 THE WITNESS: The inflammatory reaction  
21 is a granulomatous reaction.

22 BY MR. THORNBURGH:

23 Q. Right. So but Gene Kammerer says, well,  
24 therefore, the particle loss test is not relevant,  
25 unless it can be identified that the material which

1 possible that the body will try to push that particle  
2 or that loose, frayed piece out of the body, and it  
3 could come into contact with the bladder causing a  
4 bladder calculi, right?

5 MR. THOMAS: Object to the form of the  
6 question.

7 THE WITNESS: I'm not a clinician;  
8 however, I do agree with the three scenarios that Dave  
9 had proposed. I think he was correct.

10 BY MR. THORNBURGH:

11 Q. I don't know that answered my question, sir.  
12 My question to you was you never studied whether or not  
13 it was possible for these loose particles or for loose,  
14 frayed pieces of the mesh to migrate into the bladder  
15 causing a bladder calculi, right?

16 MR. THOMAS: Object to the form of the  
17 question.

18 THE WITNESS: I think it's highly  
19 unlikely, given the thickness of the muscular wall of  
20 the bladder.

21 BY MR. THORNBURGH:

22 Q. That wasn't my question.

23 My question was you never studied that issue  
24 specifically?

25 A. That's correct.